

REMARKS/ARGUMENTS

Claims 19-84, 85-86 and 91-96 are active. Claim 91 has been revised to drop the redundant term “preventing”. Claim 92 has been clarified and now describes the compound of formula I appearing in original claim 1. New claim 93 recites species previously appearing in claim 92. Claim 94 finds support in claim 92 and original claim 1. New claim 95 finds descriptive support in Examples 70-82, 86-91, 93-95, 99-101 and 105 of the specification. New claim 96 finds support in Examples 2, 5, 8, 11, 14, 17, 20, 23, 26, 29, 32, 34, 35, 41, 46, 47, 49, 51, and 53. In view of the above, the Applicants believe that no new matter has been introduced. Favorable consideration and allowance of this application are respectfully requested.

Rejection—35 U.S.C. §112, first paragraph

Claim 91 was rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement for solvates. The Applicants disagree with the Examiner’s opinion regarding lack of enablement for solvates. A “solvate” is a “compound formed by the interaction of a solvent and a solute”, see <http://www.biology-online.org/dictionary/Solvate>.

The initial burden is on the Office to establish a reasonable basis to question the enablement provided for the claimed invention, *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993), MPEP 2164.04. While the Examiner cites West, Solid State Chemistry, to assert that solvate formation or stoichiometry is not predictable, the Examiner has attempted to shift the burden of proving that “that solvates of the instantly claimed compounds actually exist” to the Applicants. West appears to be a general reference (no copy of this reference has been provided by the Examiner), and the Examiner has presented no technical reasoning why solvates of the claimed compounds of formula (I) would not form (e.g., that formula I might

lack hydrogen-bonding groups or other solvent-interactive groups, etc.) or could not be identified without undue experimentation.

Moreover, as shown by the attached documents, solvates and methods for making them were well-known in the art as of the filing date, see Sudbeck, et al., Acta Cryst. C56, 1282-1283 (2000) and Ghosh, et al., Act Cryst. C57, 76-78 (2000). Based on what is known in the art as shown by the documents above and the high level of skill of those in the art (generally doctoral or post-doctoral level), a person skilled in the art at the time of filing the present application would have been able to make and use solvates of the compound of formula (I) without undue experimentation.

Rejections—35 U.S.C. §112, first paragraph

Claims 91-92 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement for disease prevention. Claim 91 has been amended to delete the term “preventing” and Claims 91-93 are directed to the specific diseases or conditions exemplified in Pharmacological Test Examples 4 and 5. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §112, first paragraph

Claims 91-92 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description of a nexus between macrophage colony-stimulating factor and treatment of a disease. This rejection is moot in view of the amendment of these claims and limitations to specific diseases described in the specification, for example, osteoporosis and bone metastasis disclosed on page 1.

Rejection—35 U.S.C. §112, first paragraph

Claims 91-92 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement of a nexus between modulating macrophage colony-stimulating factor and treatment of a disease. This rejection is moot in view of the amendment of these claims and limitations to specific diseases described in the specification, for example, osteoporosis and bone metastasis disclosed on page 1. Moreover, Claims 91-93 are directed to the specific diseases or conditions exemplified in Pharmacological Test Examples 4 and 5.

Provisional Rejection--Obviousness-type Double Patenting

Claims 1-86 and 91-92 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claims 13-14 of U.S. Patent No 10/491,898. The Applicants respectfully traverse this rejection, since claims 13 and 14 of the copending application were amended on August 19, 2008 and no longer overlap the present claims. Specifically, in claims 13-14, R⁴⁰⁹ represents 3,3-dimethyl-butyl and not C₁₋₄ alkyl substituted t-butyl. Accordingly, this provisional rejection may now be withdrawn.

Rejection—35 U.S.C. §102(b)

Claims 1-86 and 91-92 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/43366 and WO 97/17329. This rejection is moot in view of the cancellation of claims 1-18. The compounds of formulas (Ib) to (Ig) in the have specific chemical structures which distinguish them from the compounds of the prior art.

For example, formula (I) of WO 00/43366 does not specifically disclose the substituent comprising R³² and the thiazole group of (Ib) or the corresponding substituents of (Ic) to (Ig).

Formula (VIII) of WO 97/17329 does not specifically disclose the compounds of the invention, see e.g., the disparity between “A” of formula (VIII) and the groups in (Ib)-(Ig) corresponding to R³² and the thiazole group of (Ib).

Since the prior art does not disclose the structures of the present claims, or disclose them with the specificity necessary to anticipate these compounds, this rejection may now be withdrawn.

Rejection—35 U.S.C. §102(b)

Claims 1-86 and 91-92 were rejected under 35 U.S.C. 102(b) as being anticipated by Funahashi, et al., U.S. Patent Nos. 6,797,823 & 7,253,286. The compounds in present claims 19-85 have specific chemical structures not taught by Funahashi. The Funahashi structure on page 15 of the OA has cyclopentyl and not the groups required by the present claims. Since the prior art does not disclose the structures of the present claims, or disclose them with the specificity necessary to anticipate these compounds, this rejection may now be withdrawn.

Rejection—35 U.S.C. §102(b)

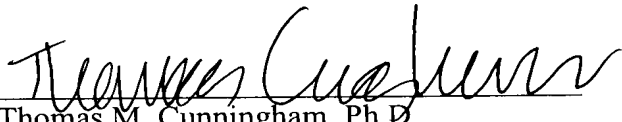
Claims 1-86 and 91-92 were rejected under 35 U.S.C. 102(b) as being anticipated by Kubo, et al., U.S. Patent No. 7,169,789 and U.S. Patent No. 6,797,823, and Sakai, et al., U.S. Patent No. 7,135,466. The Official Action does not point out any specific structures falling within the remaining claims. Present claims 19-85 require specific chemical structures not taught at all or not taught with any specificity by Kubo and Sakai. Since the prior art does not disclose the structures of the present claims, or disclose them with the specificity necessary to anticipate these compounds, this rejection may now be withdrawn.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

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